CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE
Minutes of the Meeting held on June 3, 2016
Meeting held by videoconference from CDPH Richmond campus,
KP Regional Laboratory, North Hollywood, and
Telephone Bridge Line

CLTAC members participating

Jonathan Bautista, Rhonda Becker, Richard Bennett, Patricia Dadone, Dan Dominguez, Kathleen Doty, William Gardner, Lee Hilborne, Dan Leighton, Armand Parada, Rebecca Rosser, Jennifer Schiffgens, Lu Song, Fred Ung

Former CLTAC members participating

Lorri Dean-Yoakum, Robert Footlik

CDPH staff participating

Alan Ankerstar, Elsa Eleco, Elaine Flores, Ron Harkey, Robert Hunter, Bridget Jones, Paul Kimsey, Donna McCallum, Don Miyamoto, Martha Obeso, Jan Otey, Nai Saechao, Robert Thomas, James Watt, Kathy Williams, Gilberto Wilson, Mary Wogec, Ellen Yasumura

Public members participating

Maureen Ahler, Michael Aidan, Joyce Bladel, Barbara Brunell, Tom Barrow, Mariam Castillo, Anne Chanowitz, Anna Choi, Peggy Kollars, Javier Corzon, Nathan Cron, Behnaz Dardashti, Ilene Dickman, Steve Earl Fineta, Nancy Fraize, David Gomez, Dora Goto, Brett Holmquist, Carolyn Howe, William Hurst, Jerry Hurst, Cynthia Hurst, Julie Kingery, Erica Klein, Peggy Kollars, Shiu-Land Kwong, Lois Lange, Rodney Roath, Kathy Martin, Mary McCune, Cecilia Mui, Erica Padilla, Gabriel Pineda, Colleen Suarez, Phyllis Walker, Deborah Wilson-Ferguson, Maureen Weber, Annie Yang, Tammy Zinsmeister

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Rhonda Becker. Ms. Becker thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Becker conducted a roll call of CLTAC members and other participants. A quorum was not yet met. Ms. Becker asked for Southern California to notify her should any additional CLTAC members arrive. Ms. Becker noted that Northern California would also be monitoring for additional members to arrive.

Ms. Becker welcomed and officially acknowledged William Gardner as a new CLTAC member who would be filling Lorri Dean-Yoakum's position.

Agenda Items requiring a vote were put on hold until a quorum was present.

Department update

Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), noted that he would speak on three topics.

Regarding the California State Auditors (CSA) audit, he reported that he had not heard back from the auditors. The Department submitted its Corrective Action Plan, submitted the six-month progress report, and the next progress report would be due in December. He reported that the Department is meeting all the deadlines identified in the Corrective Action Plan. He also reported that AB 1774, the bill related to the audit, was being "held under submission." The long-term status of the bill was unclear as it was being held up in committee. While the Department would update the CLTAC, information on the bill's progress can also be found on www.leginfo.com.

Lee Hilborne asked if the bill would be dropped if it did not make it out of committee. Dr. Kimsey replied that it was one possibility; bills could also be gutted and amended or otherwise moved around, so the long term status of the bill was unclear.

Dr. Kimsey reported that the American Association of Microbiology (ASM) requested that the sentinel laboratories (within the laboratory response network) complete a survey. He noted that additional information (and a link to the survey) was available on the Laboratory Field Services (LFS) website under the "News, Hot Topics, and Updates" section. Dr. Kimsey suggested that there may be a presentation about the Laboratory Response Network (LRN) at the next CLTAC meeting. He recommended that if members do not know whether or not they are a sentinel laboratory, they should visit the survey on LFS website. He explained that the network is a public health, CDC driven, federally funded and sponsored laboratory network, generally made up of governmental public health laboratories nationally. Local public health laboratories are also in touch with private laboratories within their jurisdictions. He noted that the survey was on the LFS website and it was also distributed to the LRN public health laboratory system in CA, so some may hear from them also.

Replying to a question regarding a deadline for completing the survey, Dr. Kimsey noted that he was not aware of one.

Dr. Kimsey reported that regarding Title 17 of the California Code of Regulations (CCR) Section 1050, the Department had filed the paperwork with the Office of Administrative Law to repeal the previously noted sections and the paperwork has been accepted. However, the remaining portion of Section 1050 would become outdated once the CLIA 2003 Crosswalk was officially published, which was anticipated to occur in the Fall of 2016.

Approval of minutes

Robert Thomas, Acting Branch Chief of LFS, noted a change to page 3, the spelling of Evan Sznol's first name.

Rhonda Becker noted that including herself, there was a quorum present. Lee Hilborne motioned to approve the minutes as amended. The motion was seconded by Jonathan Bautista and passed. Ms. Becker expressed appreciation for the very thorough minutes.

LFS Update

Robert Thomas welcomed and congratulated Martha Obeso, who had accepted the

position of Acting Section Chief of the Personnel Licensing Section (PLS) of LFS. She will be serving in the position while Zahwa Amad, Ph.D., is out on leave.

Mr. Thomas reported that Ms. Obeso is a public health microbiologist with over 20 years of experience in microbiology, having worked at the State's Microbial Disease Laboratory for five years as a Microbiologist II prior to coming to LFS as an Examiner II in 2012. She has since gained comprehensive experience working on CLS and MLT application approvals, training program reviews and approvals, assisting with certifying organization exam reviews, and serving as a PLS lead for the PERL online application review and approval system. She serves as a lead for the background screening that LFS performs on applicants for licensure and certification, and is also a lead for the LFS quality improvement project on phlebotomy training schools. She is also a team member working on the comprehensive update of the personnel licensing regulations.

Recognition of Robert Footlik

Mr. Thomas recognized Robert Footlik's contributions to laboratory science. Although retired, Mr. Footlik is still serving as a vital member of the CLTAC Subcommittee to Assist with Regulations and previously served as CLTAC Chair for many years. On May 13, 2016, Mr. Footlik received the American Association of Bioanalysts' (AAB) highest honor, the Lucian Dean Hertert Memorial Award. Mr. Thomas thanked Mr. Footlik on behalf of LFS for the work he has done to date and for his continued efforts, especially, on the CLTAC Subcommittee.

Mr. Footlik expressed his gratitude for LFS' recognition of his contributions and noted that he was deeply honored and humbled to be one of the few Californians to receive the award aside from Mr. Hertert himself.

Mr. Thomas recognized the work of the CLTAC in forming the three key subcommittees requested by the Department and thanked them for their work. Although the subcommittees were active and would be reporting later on in the meeting, he wished to repeat the Department's original charges in order to keep them on track.

For the CSA Audit Subcommittee, the original charge was open ended.

> "The CLTAC was charged with forming a subcommittee to assist with addressing the audit report. The Subcommittee was to decide what areas it would focus on and the Department would keep the CLTAC informed and allow it to weigh in on aspects of recommendations to the Department prior to public viewing."

For the Recruitment and Retention Subcommittee:

> "LFS is requesting a motion to create a subcommittee to assist in recruitment and retention of staff by participating in brainstorming for unique ideas to bring people on board in state service by advising on compensation analysis, training opportunities, events to target that would likely have potential candidates for recruitment, and benefit entitlements."

For the Subcommittee to Assist with Regulations,

> "LFS is requesting a motion to create an ongoing subcommittee to assist with LFS regulation packages. This subcommittee will serve as the conduit between the

industry and interested stakeholders and LFS in order to provide feedback to LFS on its regulation packages. This may include answering directed questions and review of draft language. The purpose of this mechanism is to better address consistency and clarity in LFS's regulations as well as identify possible regulatory needs."

Mr. Thomas provided an update on the status of accrediting organizations (AO) applications for the purpose of deeming laboratories to meet the requirements of California clinical laboratory law for licensure or registration. He reported that LFS approved two additional AOs for deeming authority for California in May. LFS has also received another AO application, which it is reviewing. On May 23, 2016, LFS approved the Joint Commission (JC) and on May 31, 2016, the College of American Pathologists (CAP) received its approval. Both AOs were placed on LFS' approved AO list posted on its website. He reported that laboratories that wish to use any of the approved AOs (COLA, JC, CAP) may do so following the instructions and criteria laid out in the All Clinical Laboratories Letter (ACLL) 16-01, which is posted on the LFS website.

Mr. Thomas reported that the draft of the second ACLL (16-02) is in the final stages and was set to be posted in late June. ACLL 16-02 will discuss the oversight requirements for AOs. He reiterated the importance of the public comment period of 30 days after the ACLL's posting and that the ACLL would become effective 45 days after posting and would have the force of regulation for AOs.

Mr. Thomas reported that in the coming weeks, LFS will be clarifying the details and specifics of how laboratories currently licensed and registered by the State can transition to AO oversight. LFS plans to establish a Department workgroup to address questions about process, and they will work collaboratively with the approved AOs to address issues of implementation. He reported that work had already begun regarding deemed status certificates for those laboratories that choose AO oversight at the time of their license application or renewal.

Mr. Thomas noted that LFS has had a good working relationship with COLA, and he recognized their responsiveness and support both for their accredited laboratories and for LFS' efforts and he fully anticipated the same from JC and CAP. He thanked the AOs for their interest in California deeming authority and their patience during the application approval process.

Mr. Thomas reported that LFS was asked to address the topic of "mobile phlebotomy" at the March 4, 2016, CLTAC meeting. The topic regarded phlebotomy operations, scope of practice (as related to blood collection, throat swab collection, and breath collection), patient safety, and Medicare/Medi-Cal billing. He noted that certified phlebotomy technicians (CPT) are permitted to work outside a clinical laboratory to perform phlebotomy for non-diagnostic insurance purposes or for forensic purposes when the CPT follows policies and procedures established by a physician and is supervised by a physician, nurse, or a person licensed under the California Business and Professions Code (BPC) Chapter 3, which includes a medical laboratory technician. He noted that given the complexity of this issue and level of interest, it would require a fuller discussion than time would allow during that June CLTAC meeting. He noted that more time would

be allotted for discussion of this issue at the September meeting.

CLIA Crosswalk

Rhonda Becker thanked everyone who participated in the electronic vote on the CLIA Crosswalk stringency guidelines. The vote was unanimous, and the guidelines were accepted.

Kathy Williams, Section Chief of Facility Licensing, thanked those who worked on the Crosswalk. She reminded members that their participation is still needed as LFS begins Phase 3 (Phase 1 was the Crosswalk itself and the recommendation of the Subcommittee to the full CLTAC. Phase 2 was the full CLTAC voting on the recommendation). Ms. Williams read a brief statement into the record submitted by Tammy Pahland, House Counsel for LFS. It read as follows:

> [Ms. Pahland] has submitted to the Office of Regulations documents which include the justification and background for the decision to either accept, reject or implement the parts of CLIA 2003 that we reviewed. Once that review is completed, [the Office of Legal Services] will package it with a form for the Chief Counsel's signature to submit to Office of Administrative Law for publication. OLS expects that package to be published by the end of June.

She reported that the June deadline was only an expectation. CLIA 2003 will remain on the agenda until the final phase is concluded, which includes the regulation package that implements those items the Department determined to be less stringent.

Legislation update

Mary Wogec, Legislative Coordinator for LFS, presented updates on a number of Senate and Assembly bills.

Ms. Wogec reported that AB 1774 (Clinical Laboratory Licensing), introduced by Assembly Member Susan Bonilla on February 24, 2016, was amended on April 25, 2016 and May 11, 2016. It amends 12 sections of the Business and Professions Code (BPC); it repeals 15 sections of the BPC; adds section 1272.1 to the BPC, amends section 9272; amends sections 1206 and 1600.3 of the Health and Safety Code, and amends section 14043.27 of the Welfare and Institutions Code. LFS received a fact sheet from the author's office containing letters of support and opposition from various organizations. Dora Goto, representing the California Association for Medical Laboratory Technology (CAMLT), stated that their May 10, 2016, registered letter of opposition did not appear on the fact sheet.

The bill is currently held under submission in the Assembly Appropriations Committee. Ms. Wogec explained that this refers to an action taken by any committee when a bill is heard and there is an indication that the author or committee members wants to work on the bill further and there is no motion for the bill to progress out of that committee. That is where this bill is now.

Ms. Wogec reported that AB 2179 (Hepatitis C Testing), introduced by Assembly Member Mike Gibson on February 18, 2016, was amended on March 28, 2016, March 30, 2016,

and April 14, 2016. LFS was assigned to secondary analysis. The bill would authorize a Hepatitis C Counselor, who meets specified requirements, to perform HCV tests in the manner described in the bill with respect to HCV testing by an HIV counselor. It is currently in the Senate after having passed the Assembly. The bill has numerous organizations supporting it and none opposing.

Ms. Wogec reported that AB 2750 (Tissue Banks) introduced by Assembly Member Jimmy Gomez on February 18, 2016, was amended on March 17, 2016, April 7, 2016, and May 23, 2016. LFS is assigned primary analysis. The bill amends section 1635.1 of the Health and Safety Code. AB 2750 would create an additional exemption from the tissue bank licensing requirement for the storage of allograft tissue by a person if that person is a hospital or outpatient setting, the person maintains a log including specified information pertaining to the allograft tissue, and the allograft tissue meets specified requirements, including, among other things, that the allograft tissue was obtained from a California-licensed tissue bank, is individually boxed and labeled with a unique identification number and expiration date, and is intended for the express purpose of implantation into or application on a patient. The bill is supported by MiMedx. There are no letters of opposition.

Ms. Wogec reported that SB 622 (Optometrist Scope of Practice) introduced by Senator Ed Hernandez on February 27, 2015, and amended on April 9, 2015, and May 4, 2015. It is a two-year bill. The bill amends sections 3041 and 3110 of the BPC. It adds five sections to the BPC and repeals and adds sections 3041.1, 3041.2 and 3041.3 to the BPC.

Ms. Wogec reported that SB 1316 (Human Milk Tissue Banks) authored by Senator Lois Wolk and co-author Assembly Member Cristina Garcia, was introduced on February 19, 2016 and amended on April 14, 2016. This bill would define “human milk tissue bank” as a tissue bank that provides financial compensation to a participating mother for procuring human milk for the purpose of human consumption. It defines “participating mother” as a woman who provides her human milk to a human milk tissue bank in exchange for financial compensation. It would require the tissue bank to work with lactation support groups to provide breastfeeding education and lactation support. It would prohibit the tissue bank from procuring human milk from a mother within her first 180 days postpartum. The bill would require the adoption by the Department of rules and regulations governing human milk tissue banks substantially based on guidelines of the Human Milk Banking Association of North America. The bill is currently held in Committee under submission. There were many letters of support for the bill and four against.

Ms. Wogec reported that SB 1408 (Tissue Donation) introduced by Senator Ben Allen on February 18, 2016, and was amended on April 13, April 18, May 4, May 23, and May 26, of 2016. The bill was enrolled and chaptered on May 26, 2016, to introduce an urgency clause. The bill has been signed by the Governor and is now in effect as law. Current law authorizes the transplantation of tissue from a donor who has not been tested for specified infectious diseases or, with the exception of HIV and HTLV, has been found reactive, if specified conditions are satisfied. This bill would delete the exception of HIV from this provision. The bill would require a physician and surgeon performing the transplantation of an organ from an HIV-reactive donor to ensure that the recipient is also

HIV reactive and complying with the federal law, as specified. The bill declares that it is to take effect as an urgency statute. There were numerous letters of support and none in opposition.

Ms. Wogec reported on SB 1418 (Medi-Cal Immigration Status) authored by Senator Ricardo Lara, which was originally introduced by Senator Cathleen Galgiani on February 19, 2016. The original bill was amended on March 28, April 13, and April 26 of 2016, by Senator Lara. The bill as amended would extend eligibility for full-scope Medi-Cal benefits to individuals 19 years of age and older who are otherwise eligible for those benefits but for their immigration status if the State Department of Health Care Services determines that sufficient funding is available, or for limited scope Medi-Cal benefits if funding for full-scope benefits is not available. The bill would require these individuals to enroll into Medi-Cal managed care health plans, and to pay copayments and premium contributions, to the extent required of otherwise eligible Medi-Cal recipients who are similarly situated. The amended version of the bill no longer concerns LFS and LFS is not required to provide an analysis.

Subcommittee reports

Rhonda Becker expressed appreciation for the actions taken by the various subcommittees.

Jonathan Bautista, Recruitment and Retention Subcommittee Chair, reported that he has been working with Ms. Ellen Yasumura to coordinate meetings with the Committee. He reported that there have been two meetings since December 2015, but noted there was a lack of clarity to address the charge. He was subsequently able to clear things up with Ms. Yasumura and is now working with Sarah Rutschmann to get the Subcommittee back together again and they should be able to be address the issues quickly.

Fred Ung, CSA Audit Subcommittee Chair, reported that the Committee has not met since the last CLTAC meeting because they have been waiting for additional documentation from LFS. Paul Kimsey reported that they had anticipated more interaction with the CSA, which has not yet materialized.

Lee Hilborne, Regulations Subcommittee Co-chair, thanked the Subcommittee members for their contributions and expertise, and noted they had been very busy. He reported that the group prioritized the issues presented to it by the Department and of those discussed, the Subcommittee presented five issues that it had settled to the full CLTAC. Should the CLTAC agree with the Subcommittee's recommendations, the Department would then take the CLTAC's recommendation into consideration with regards to regulations and policy. The Subcommittee would also draft related FAQs for the Department's consideration for posting on the Department's website.

Referencing the two handouts on his topic, Dr. Hilborne summarized the Subcommittee's views on five issues.

1. Regarding the definition of "supervision and control," the Subcommittee's goal was to be as permissive as possible within the context of the existing statutes and regulations while reflecting current practice to the extent that it represents quality care. With a focus

on unlicensed personnel working at patient service centers or draw stations, supervisors can be physically present or available by telephone or electronic means as there is no evidence that there is a quality problem with having supervision available remotely.
2. Regarding the definition of "employed by," the term does not necessarily mean the phlebotomist is compensated by the clinical laboratory, but the phlebotomist and laboratory must satisfy the requirements found in Section 1246 of the Business and Professions Code.
3. Regarding "accountable to," the designee responsible for oversight is either directly or indirectly responsible to the laboratory director for the issues related to the clinical practice and the supervision that they are providing.
4. Regarding whether a phlebotomist can supervise another phlebotomist, the question arose concerning whether a CPT I can supervise a CPT II. The Subcommittee suggested that a CPT I can supervise a CPT II as long as the activities that the CPT I is supervising are those that are within the scope of practice of a CPT I.
5. With respect to foreign applications, LFS raised a question regarding types of training that would be deemed acceptable. The Subcommittee looked to the American Society for Clinical Pathology's Board of Certification language, which states that training and experience must be obtained through a lab accredited by CAP, Joint Commission International or ISO 15189 accrediting agency. The applicant produces a certificate which is then verified by the Board of Certification.

Dr. Hilborne reiterated that these were just the first five topics resolved and there would be more to come. Additionally, while the CLTAC could make recommendations to the Department to clarify regulations, only the Legislature could make changes to statutes. It was also noted that the Subcommittee would begin on the FAQ documents.

Replying to a question on the Subcommittee's view of current trends regarding "mobile phlebotomy," Robert Thomas deferred the question to the next CLTAC meeting, as the matter involved numerous issues that could not, then, be adequately addressed due to the meeting schedule.

Ms. Becker recognized Dr. Hilborne's request to call for a full CLTAC Committee vote on the five items presented in the Subcommittee report and, with no second required, called the vote. There were no abstentions or 'no' votes.

Ms. Becker requested that as Subcommittees reach milestones or closure on certain issues, they bring them forward to the full CLTAC for a vote.

Electronic Laboratory Reporting

James Watt, MD, discussed three topics: electronic laboratory reporting (ELR), laboratory reporting regulation update, and Zika virus.

Dr. Watt reported that ELR continues to expand in California and that it is valuable for public health. Electronic laboratory reporting has increased the timeliness of reporting and the ability to identify outbreaks. It has also increased the ability to efficiently manage large amounts of data.

The California Department of Public Health (CDPH) is looking forward to electronic

submission from Electronic Health Records (EHR). Dr. Watt reported that the integration of EHR was developing much faster than he anticipated. He added that piloting was expected as early as 2017 and a larger rollout was expected in 2018-2019. EHR may have an impact on how laboratories report and will require further discussion. He reported that CDPH has begun receiving approximately 20,000 unique disease incident reports through ELR per month. There are now over 300 laboratories submitting reports via ELR.

Dr. Watt presented a Title 17 update. CDPH added five new conditions that are laboratory reportable. These conditions are: Babesiosis, Chikungunya Virus infection, Flavivirus infection of undetermined species, *Entamoeba histolytica* (not *E. dispar*) infection and Zika Virus infection. Chikungunya Virus infection, Flavivirus infection of undetermined species and Zika Virus are a response to what is happening in Latin America with the spread of mosquito-borne virus and viral illnesses. There are three new specimens that are required to be submitted: Zika virus immunoglobulin M (IgM)-positive sera, drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only) and *Shigella* isolates.

The biggest change surrounding Title 17 regulations involves the new requirement for culture independent diagnostic tests. Dr. Watt stated that this is an area that has been growing and will continue to grow. The concern is that as culture independent diagnostic testing expands the traditionally collected isolates will become less available for public health work. Laboratory regulations have a new section which requires that if there is a positive culture independent test, laboratories will attempt isolation so that they can still submit the isolates that have been historically submitted. The isolates include: drug resistant *Neisseria gonorrhoeae* isolates, *Listeria monocytogene* isolates, *Mycobacterium tuberculosis* isolates, *Neisseria meningitides* isolates from sterile sites, *Salmonella* isolates, Shiga toxin-producing *Escherichia coli* (STEC) isolates (including O157 and non-0157 strains) and *Shigella* isolates.

Dr. Watt noted that these changes will be delivered in writing in the near future so that they may be implemented in the reporting systems. Dr. Hilborne commented that these changes represented more than a change in the reporting system, adding that the changes would require that laboratories collect specimens using the traditional mechanisms as well. Dr. Watt agreed.

Zika Update

James Watt, MD, discussed the emergence of Zika virus in the Americas and what it means for California. In May 2015, an outbreak of Zika was discovered in Brazil; by April 2016, Zika has spread to 40 countries and territories in the Americas and Pacific Islands. There is some concern that the virus may spread back to Africa as it was recently identified on an island off the coast of Africa.

Zika is an illness caused by Zika virus. It is a mosquito-borne flavivirus. *Aedes aegypti* is the primary vector. *Aedes albopictus* is the secondary vector in California. These mosquitoes are not native to California, but there are isolated populations of these mosquitoes around California. The most common symptoms of Zika are fever, rash, joint pain, and conjunctivitis. The concern is that this virus is spreading widely in the Americas and has now been shown to cause severe neurologic disabilities in newborns, particularly

microcephaly. As a consequence, the Center for Disease Control (CDC), the World Health Organization (WHO) and the CDPH have recommended that pregnant women or women planning to become pregnant should not travel to areas with active Zika virus transmission. Zika virus has also been associated with Guillain-Barré Syndrome. The Syndrome is very likely to be triggered by Zika virus in small proportion of infections. For those who must travel to active outbreak areas, the appropriate protective measures should be taken.

Additionally, the spread of the Zika virus through blood transfusion has been reported. CDPH has been working with the California Association of Blood Centers to make sure CDPH has good communications with them so that they can implement their FDA required screening to keep the blood supply safe in California. In the last two years, CDPH has identified 50 cases of Zika virus infection, all of which have been associated with a person who traveled to a region with a known Zika outbreak. Eleven of the individuals were pregnant at the time of their diagnosis. Out of the 50 cases 36 were residents of counties with the invasive *Aedes* and 36 were potentially viremic while in California. There are no cases of mosquito transmission in California.

Coupled with the 7-10 day incubation period of Zika in the mosquito and mosquitos only living 14-21 days, the patchy distribution of the *Aedes aegypti* and *albopictus* makes it unlikely that mosquito transmission would occur in the United States. Given this and other mitigating factors, he concluded that it is unlikely that the United States would experience the extensive outbreaks found elsewhere.

Sharon Messenger, Ph.D., the Section Chief of the Zoonatic and Vectorborne Disease section of VRDL, presented a laboratory update on Zika. One of the missions of her Section is to do laboratory testing for arboviruses. She emphasized that laboratory diagnosis of arboviral diseases is one of the most complicated and challenging diagnostic tests that the Section performs, often involving a combination of rule-in and rule-out tests in order to accurately diagnose a recent infection and identify the appropriate virus that may be causing the infection. Historically, VRDL has maintained a large number of assays to test for a broad array of arboviruses. An increasing number of exotic arboviral diseases makes the challenge of maintaining a large number of assays that much greater. Building upon experience with West Nile virus testing, VRDL has been actively working on laboratory testing for Zika and other exotic mosquito borne diseases such as dengue and chikungunya over the last two years.

Dr. Messenger discussed what is needed from the laboratory to help confirm an arbovirus case; specifically, evidence of a recent infection from a specific arbovirus. There are different ways that this can be approached; direct detection of the virus, (establishing both timing and specificity) via viral nucleic acid detection, virus isolation, and viral antigen detection or, more commonly, via serological evidence of recent infection with specific arbovirus.

Zika is a flavivirus and is genetically closely related to several other flaviviruses of concern, including dengue virus, West Nile virus, Japanese encephalitis virus, and Yellow fever virus. Like dengue and chikungunya, *Aedes aegypti* is an important vector for all of these viruses. The main concern in the current outbreak in the Americas is that both

dengue and chikungunya viruses are also co-circulating in many of these countries. In order to really establish a Zika virus infection in any suspect patient, laboratory testing is critical in determining what is causing that infection.

The recent knowledge gained has been providing a lot of the rationale for the CDC testing guidance. The CDC realized that both molecular and serological tests were going to be necessary to properly detect Zika virus in individuals. She noted that VRDL is closely following the CDC guidelines and have established all of those tests and there is also the capability to do molecular testing as well as IgM testing.

When news of Zika virus initially came out in 2014 and 2015, CDPH passed along Zika test samples to the CDC for testing. Beginning in January 2016, CDPH began testing the Zika samples directly after acquiring new tests such as PCR, IgM/IFA and PRNT so that all testing could be conducted in-house. Reviewing the relative strengths and weaknesses of the various tests, she noted that while they had weaknesses individually, together, they compensated for one another.

CDC has offered to roll out to nine of the 14 Laboratory Response Network (LRN-B) labs in California access to the FDA emergency use authorized tests. In counties where there is not a LRN-B lab, CDC has provided a singleplex Zika virus PCR. Dr. Messenger stated that there is a close relationship with these laboratories to validate those tests. She emphasized the importance of collecting urine in addition to the serum samples. She stated that there are still limitations to the diagnostic testing and a fairly conservative approach is desired in how the test results are interpreted and managed.

Dr. Messenger was asked about the two testing platforms by the IND by the Red Cross and Blood Systems for Zika virus screening of blood donations. Blood donation testing is something that is to be reviewed for immediate use, however there is not a test at this point for blood banks. Dr. Watt added that the testing is something the larger blood organizations hope to start soon and noted that the blood banks are recording asymptomatic blood donors who may be identified through testing.

To a question regarding the testing capacity should the Zika situation grow, Dr. Messenger responded that there are additional laboratories trying to come online with both serological testing, PCR, and IgM which will be an immense help. Though there are no local transmissions of Zika virus within the continental United States, the CDC is currently performing modeling to try to estimate what surge testing demands may be and plans are being developed amongst various state partnerships, which includes plans for assistance.

Personnel Licensing Section Update

Martha Obeso reported that the Personnel Licensing Section has been very active with the Director applications and 18 licenses have been approved. The last oral exam took place in May. The next oral exam is scheduled for August 8 and there are five candidates. An additional exam will be scheduled for September—the specific exam date has yet to be determined.

Ms. Obeso reported that there are 106 accrediting agencies for continuing education on

the LFS website. Eighty-five of the agencies have been approved for renewal and the certificates have been mailed. The remainder of the accrediting agencies have until eighteenth of June to respond before being removed from the list.

Ms. Obeso reported that the National Health Career Association's (NHCA) initial application for phlebotomy certification was approved in early-May. The American Association of Bioanalysts Board of Registry's renewal for clinical laboratory scientists and medical laboratory technicians was approved in April.

Ms. Obeso added that the phlebotomy section had a 45-day average turnaround for new phlebotomy certifications. She reported that in the scientists and trainees section, LFS is prepared for the summer increases as trainees graduate. LFS receives 50-100 new applications per week. She noted that the renewal section was current and applications received in June were the focus. She added that some applicants had complained about the PERL payment system. The issues were estimated to be resolved in a matter of days.

Replying to a question regarding application turnaround times, Ms. Obeso confirmed that the new phlebotomy certification review time by LFS was shorter than it had been previously, and that the review time was actually between 30 to 45 days for approval.

Regarding questions concerning whether CPTs who had been on inactive status for more than five years were required to retake the exam and whether there was a difference between inactive status and lapsed status as with CLSs, it was reported that that with the CLS, MLT, and Director category licensures, the license can go inactive and can remain inactive for five years. At the end of five years the license is forfeited and the person must go through the reevaluation process or take another exam. However, a phlebotomist license goes inactive, the certification is not forfeit, and the exam does not need to be retaken but continuing education requirements must be met prior to the renewal.

Regarding the CLS timeline for approval, Ms. Obeso stated that the CLS wait time is a little longer. She noted that a couple of issues can affect turnaround time (and the average turnaround time): phlebotomy applicants can upload most of their documents through the application, while CLS, MLT, and Director documents must come directly from the source; and CLS, MLT, and Director applicants are allowed to submit their application while working towards fulfilling all their licensure requirements. Ms. Obeso reported that LFS is processing the CLS applications efficiently through the PERL system and that if everything is submitted in a timely manner, review can be completed in less than a month.

CLIA Survey Section Update

Donna McCallum, CLIA Survey Section Chief, reported that IQCP became the effective on January 1, 2016. She emphasized that on both the CMS-CLIA website and the CDC website, there is a complimentary workbook that can be downloaded. The workbook helps laboratories establish IQCP. The workbook was developed through a collaboration between CDC and CMS. She reported that the Interpretive Guidelines revision as of January 2016 was completed. As of January 1, 2016, the "laboratory must be in compliance with either their choice of default regulations or adopt an IQCP plan."

Ms. McCallum reported that in 2014 there were a lot of conversations about a CLIA modernization proposal. The FDA submitted a proposal draft document for oversight of laboratory developed tests to Congress; it was also posted for public comment. Opponents argued that CMS-CLIA programs already sufficiently covered lab developed tests and that the proposal would bring an undue burden for the laboratories and that both agencies have some duplicate oversight regarding laboratory developed tests. Opponents also argued that labs do not function as manufacturers and that the FDA does not have authority over the laboratories. She reported that both CMS and FDA have explained the difference between the statutory authority and the responsibility on numerous occasions. She noted that there are FAQs posted on the CMS-CLIA website that outlines the responsibility of CLIA as well as the oversight and responsibility of the FDA in regards to the laboratory developed tests.

Ms. McCallum noted an effort to streamline laboratory developed test oversight. She reported that there is a focus to identify the duplication of duties and the differences and then work through those differences. Ms. McCallum stated that CMS is aware of the development of four proposals for legislation regarding the CLIA. The four proposals are from the American Medical Association, the Association of Molecular Pathology, the College of American Pathology, and the Diagnostic Test Working Group. She noted that these proposals differ in their clarification of laboratory developed tests, but the oversight responsibility should be covered by CMS verses FDA and implementation guidelines. She gave some background on the collaboration between CMS and the FDA. She noted that additional proposals have been written: The Revision and Enhancement of CLIA Regulations, Site and Oversight Responsibilities for Manufacturing Requirements of Laboratory Developed Tests, and Requirement of Both Analytical and Clinical Validation Data for Laboratory Developed Tests.

Regarding whether all AOs accept IQCP as an option, Ms. McCallum reported that all of the AOs have gone through the CMS approvals. She reported that each of these AOs had to present an updated copy of their standards to include IQCP. She added that if someone wanted to know if an AO accepted or did not accept these, each individual AO must be contacted directly.

Regarding whether there was a draft of the FDA document on wellness testing, Ms. McCallum directed everyone to the MMWR, which has additional information.

Tissue Bank, Blood Banks, and Biologics Section Update

Ron Harkey, Tissue Bank, Blood Bank, and Biologics Section Chief, noted that there was a lot of activity in all areas. He stated that not much data is available to report as the Section was asked to share data at a later time.

He reported that Bob Hunter has been working closely with the Blood Centers of California in regards to a number of issues, including Zika reporting and also potential testing for blood banks to cover donors in the future. He reported that Mr. Hunter has also been working with the Blood Centers to update the Paul Gann Blood Safety Act brochures. The pamphlets were updated due to the number of changes since the last publish date.

He reported that the Section is working on the revision of protocols for Transfusion Related Incident (TRI), which actually takes place within clinical laboratories and not blood banks. He stated that the Section is working along with the Licensing and Certification branch of CDPH, the FDA, and the blood centers.

He reported that there are many bills that have affected tissue banking, as covered by Ms. Wogec earlier in the meeting. He added that staff had been working diligently on those bills. He reported that questions are continually arising related to human milk that have not been addressed at that point, noting that the Section had worked hard to answer questions that the Legislative and Governmental Affairs Office had in those areas. He added that the team continues to work with the 800 tissue banks, which have been growing in number. This data will be available for the next meeting.

He reported that Don Miyamoto was working on the continuous updates of the pathology information that laboratories are sending in terms of the kind of cytologists that they hire and making sure that those numbers correspond to the information on hand. He noted that the California laws are more comprehensive than the CLIA laws and this is still under close review.

Facility Licensing Section Update

Kathy Williams, Facilities Licensing Section Chief, noted that Facility Licensing is undergoing many changes currently in response to both the audit and CSA's recommendations that were made for the realignment of some services. Ms. Williams thanked former retirees who had left the Department recently: Shideh Kashe, who had worked in both out-of-state laboratories and complaints; Dale Statly, who was the onsite initial survey examiner and helped with complaints investigations; Pat Toomer, who reviewed proficiency testing and administered the service provided to states who wanted to use the California electronic format for proficiency testing reporting; Karen Demby, who is not retiring but moving on in her career to a position outside of state service. They all contributed greatly to the laboratory community.

Dr. Hilborne asked when additional information would be available with regards to the audit. Ms. Williams responded that more information would be presented as it becomes available, confirming that the information would track with the audit-report reporting.

Debbie Ferguson asked if the departures will affect the time is takes for facility licenses to be reviewed. Ms. Williams responded that they will not as there are program technicians in place to process them.

On-Site Licensing Section Update

Elsa Eleco, On-Site Inspection Section Chief, noted that, as mentioned in the meeting in March, there would be an increase in the number of routine in-state and out-of-state inspections, surveys, and complaint investigations. She received a significant number of inquiries from people about the cause of the inspection increase. She noted that the inspectors are just doing their jobs. She reported that facilities should expect to have increased unannounced on-site inspections, surveys, or phone calls.

Ms. Eleco welcomed a new addition to the Section, Gilberto Wilson, a staff services

analyst. Mr. Wilson joined the Section in April. He is a recent graduate of California State University, San Bernardino, where he received his bachelor's degree in Health Science with a minor in Information Systems and Technology. He has a strong background in computer and systems development. He will primarily be assisting with the intake of complaints. She reported that Mr. Wilson will likely be sending acknowledgment letters when complaints are sent. Ms. Eleco reiterated that the current inspections are routine in nature.

Ms. Becker asked that statistics, similar to what had been presented in the March meeting, be presented in the near future.

New Business

Rhonda Becker presented a new business item for CLTAC consideration. Ms. Becker gave a brief background on CLTAC bylaws regarding members. Ms. Becker noted that the appointees to the Committee can serve no more than two consecutive four-year terms. The CLTAC calendar goes from January 1 to December 31. The chair serves the same calendar year and is also limited to no more than two consecutive four-year terms. However, as the bylaws are written, the Chair is elected at the December meeting but does take over until after the June meeting, which leaves a gap of six months and creates an administrative issue. Ms. Becker requested a review of the bylaws and an amendment to Article 3, to read, "Committee chair shall be elected annually by the members at the December meeting to serve for the following year beginning in January." This removes any gap in service by the Chair.

Kathleen Doty moved that the CLTAC amend Article 3 of the bylaws such that the election of the Chair would still occur in December but that their term of office would begin in January. Dr. Hilborne seconded the motion.

Dr. Hilborne asked if the change to the bylaws required public notice. Ms. Becker responded that the CLTAC bylaws do not require public notice but the bylaws do state that to amend the bylaws a two-thirds vote of the voting members of the full CLTAC. The full CLTAC is a twenty-one member Committee. Fourteen members voting in favor would be needed to pass the amendment.

Jennifer Schiffgens asked about the "on-boarding" process for the new Chair to bring them up to speed on the Committee's activities. Ms. Becker explained that the incoming Chair of the Committee has typically served on the Committee for a period of time. She added that it is incumbent upon the incoming Chair to reach out to the previous Chairs and other CLTAC longstanding members for guidance in his or her new role. Dr. Hilborne added that it would be unlikely that the current Chair would leave suddenly.

Ms. Becker called the motion to a vote for amending Article 3 of the bylaws, "Committee chair shall be elected annually by the members at the December meeting to serve for the following year beginning in January." Fourteen CLTAC members voted in favor of the amendment, with no votes against. The amendment passed.

Bob Thomas added that Article III also stated that, "At the time of their appointment licensed members shall be actively and currently engaged in clinical lab activities

requiring the use of their licenses." A committee member may serve up to two consecutive four-year terms and there have been members who, at the time of their appointment, were actively and currently engaged in clinical lab activities. A person could retire during the period of their appointment. The concern is their eligibility to be re-appointed if they retire during the course of their appointment and are no longer actively and currently engaged in clinical activities requiring the use of their license. Ms. Becker's understanding was that they were not eligible, as they were not currently involved in clinical lab activities at the time of their appointment. After further discussion the question was reduced down to whether or not the term appointment was tied to the term reappointment in such a way as to require the licensing condition be applied to the reappointment.

Ms. Becker asked the CLTAC members to review the bylaws related to appointment and reappointment in advance of the next meeting. Ms. Becker asked that bylaw review be added as an agenda item for the next meeting. The bylaws are available online.

A CLTAC member proposed the consideration of a chair-elect. Ms. Becker responded and asked that the member put together a plan in support of a chair-elect at the September meeting.

Future Items

A CLTAC member asked for a status update on the search for the Chief of Field Laboratory Services. Mr. Thomas stated that an exam had been given and as a result of the exam, upcoming interviews may be scheduled. Ms. Becker asked that at the next meeting Dr. Kimsey share the status of the search.

Next Meeting

Ms. Becker noted that the next meeting is scheduled for September 9, 2016. December 2, 2016, is the last meeting for 2016.

Ms. Becker thanked everyone for their time and attention, voting and progress made on a number of fronts.

Adjournment

Lee Hilborne motioned to adjourn and the motion was seconded by Jonathan Bautista. The CLTAC board voted to adjourn at 11:55 a.m.